

ELECTROSURGICAL HEMOSTATRelated US Application Data

5           This application claims priority from US Provisional Patent Application No. 60/422,330 filed October 30, 2002, incorporated herein by reference in its entirety.

Background of the Invention

10           The present invention relates to surgical tools and procedures generally and relates more particularly to the use of electrosurgical ablation to treat atrial fibrillation.

          In patients with chronic atrial fibrillation or having atrial tachycardia that is resistant to medical treatment, the Maze III procedure has been employed. This procedure  
15           controls propagation of the depolarization wavefronts in the right and left atria by means of surgical incisions through the walls of the right and left atria. The incisions create blind or dead end conduction pathways, which prevent re-entrant atrial tachycardias from occurring. While the Maze procedure is successful in treating atrial fibrillation, the procedure is quite complex and is currently practiced by only a few  
20           very skilled cardiac physicians in conjunction with other open-heart procedures. The procedure also is quite traumatic to the heart, as in essence the right and left atria are cut into pieces and sewed back together, to define lines of lesion across which the depolarization wavefronts will not propagate.

25           It has been suggested that procedures similar to the Maze procedure could be instead performed by means of electrosurgical ablation, for example, by applying radiofrequency (RF) energy to internal or external surfaces of the atria to create lesions across which the depolarization wavefronts will not propagate. Such procedures are disclosed in US Patent No. 5,895,417, issued to Pomeranz, et al., US  
30           Patent No. 5,575,766, issued to Swartz, et al., US Patent No. 6,032,077, issued to Pomeranz, US Patent No. 6,142,944, issued to Swanson, et al., US Patent No. 5,871,523, issued to Fleischman, et al. and US Patent 6,502,575, issued to Jacobs et

al., all incorporated herein by reference in their entireties. Hemostat type, electrosurgical or cryo-ablation devices for use in performing such procedures are described in US patent No. 5,733,280 issued to Avitall, US Patent No. 6,237,605 issued to Vaska, et al, US Patent No. 6,161,543, issued to Cox, et al., PCT published Application No. WO99/59486, by Wang and in pending US patent application SN 09/747,609 filed December 22, 2000 by Hooven, et al., all incorporated herein by reference in their entireties. In order for such procedures to be effective it is desirable that the electrosurgically created lesions are continuous along their length and extend completely through the tissue of the heart (i.e. transmural lesions). These goals may be difficult to accomplish employing dry ablation electrodes or electrodes applied only to the interior or exterior surfaces of the heart tissue. Electrosurgical hemostats configured to allow fluid – assisted tissue ablation are generally described in US Patent No. 6,096,037, issued to Mulier, also incorporated by reference in its entirety.

#### Summary of the Invention

The present invention provides an ablation hemostat, particularly useful in performing a maze type procedure by applying ablation energy (e.g. RF energy) across the walls of the left and right atria by means of delivery means located on either side of the atrial walls. In a preferred embodiment of the invention, the hemostat is provided with elongated RF electrodes malleable to assume various straight and curved configurations to produce lesions that approximate the incisions that would occur during the Maze III procedure as described in the book 'Cardiac Surgery Operative Technique' by Donald B. Doty, M.D. at pages 410-419, incorporated herein by reference in its entirety, or to allow creation of lines of lesion corresponding to the incisions that would be provided by other forms of the Maze procedure. The hemostat may be useful in conjunction with other procedures as well.

The hemostat of the present invention is provided with a number of useful features, particularly adapted to ease its use in conjunction with creating elongated lines of lesion. While the disclosed and most preferred embodiments of the invention employ all of the improved features, each of the improved features discussed below is

believed valuable in and of itself to improve the performance and ease of use of prior art electrosurgical hemostats.

5 In order to allow the hemostat to produce straight and curved elongated lesions, the jaws of the hemostat are malleable to allow the physician to set the specific jaw configuration. The jaws are fabricated of a flexible plastic sheath enclosing elongated bendable or malleable backbones and electrodes to achieve this result. The backbones and electrodes may be shaped by the physicians' fingers into a desired curvature and serve to retain the curvature imparted to them until reshaped for creation of a  
10 subsequent lesion. The backbones take the form of elongated plates having thicknesses substantially less than their widths to encourage bending of the jaws within a single plane so that the opposed electrodes can more readily be maintained in alignment along their lengths. The backbones are also preferably tapered along their length such that the width of the backbones diminishes as they approach the tips of the  
15 jaws, in turn making it easier to provide the jaws with the curvature extending over the entire length of the jaws.

The hemostat includes an elongated handle portion or handle and a jaw assembly mounted at the distal end of the handle. The jaw assembly preferably includes two  
20 elongated jaws carrying RF electrodes or other ablation elements, extending along the lengths of the jaws and arranged so that they are located on opposite sides of tissue compressed between the jaws. In preferred embodiments, the electrodes take the form of fluid irrigated RF electrodes, however, other ablation mechanisms such as cyroablation, direct current ablation, microwave ablation, and the like may be  
25 substituted for RF ablation electrodes.

The jaw assembly preferably includes a swiveling head assembly adapted to allow the jaws to be rotated relative to the axis of the handle (roll) and allowing the jaws to pivot around an axis perpendicular to the axis of the handle (pitch). Adjustment of the  
30 jaws relative to the handle (pitch and roll) is made manually by the physician, and the jaws are retained in their desired orientation relative to the handle by means of detent mechanisms.

The jaws are mounted to one another at a pivot point and are opened and closed by means of a trigger, mounted to the handle, which applies tensile force to a cable or other tension member extending along the handle. The cable, when pulled, pulls the jaws toward one another to compress tissue between them. In the particular embodiments disclosed, the cable is anchored offset from the pivot point to a first one of the jaws. The first jaw is fixed, i.e. retains its location during jaw closure regardless of the pitch and roll adjustment made to the jaw assembly. The second, pivoting jaw, is mounted to the fixed jaw at a pivot point and the cable passes around an internal boss within the pivoting jaw, also offset from the pivot point. Application of tension to the tension member pulls the internal boss in the pivoting jaw toward the cable mounting point in the fixed jaw and thereby causes movement of the jaws toward one another. Tissue placed between the jaws can thus be engaged by the jaws and compressed between the jaws as the jaws close.

The cable enters the jaw assembly along its rotational (roll) axis, so that rotation of the jaw assembly about the roll axis does not alter the operation of the cable. The cable extends around a shoulder internal to the fixed jaw, which shoulder remains essentially in the same location regardless of the pitch adjustment of the jaw assembly, so that pitch adjustment of the jaw assembly does not significantly effect operation of the cable to close the jaws.

In preferred embodiments, the trigger mechanism is provided with a locking detent mechanism which may be engaged or disengaged and which, when engaged, retains the trigger in its position, in turn maintaining compression of the jaws against tissue located there between. The detent mechanism in a preferred embodiment is activated or deactivated by means of a sliding button, mounted to the handle.

In preferred embodiments, irrigation fluid is provided to the electrodes by means of plastic tubing that is provided with in-line flow limiters, controlling the delivery rate of irrigation fluid to the electrodes. This feature allows the use of a simplified fluid pumping mechanism and also provides balanced, even fluid flow to the electrodes. In

its preferred embodiment, the trigger, when released, also serves to block fluid flow to the electrodes, preventing irrigation while the hemostat is not in use.

In one embodiment, the RF electrode assembly can take the form of an elongated porous material coupled to the fluid delivery lines and carrying elongated electrode wires on their inner, facing surfaces. The electrode wires may be coupled to the porous material by means of a series of spikes extending from the electrode wires into the porous material. Other alternative electrode designs may of course be substituted, including electrodes comprised of elongated coil electrodes or perforated tubular electrodes with porous material located either inside of or surrounding the electrodes. For example, a perforated tubular electrode can be seated inside a porous polymeric support such the electrode is entirely within the support. In this embodiment, conductive fluid flows through the interior of the electrode, out of perforations in the electrode and through the porous support to facilitate ablation such that the polymeric support, not the electrode, is on the facing surfaces of the jaws to contact the tissue to be ablated.

The hemostat may optionally also include a thermocouple, located along the jaws allowing for temperature controlled feedback of power provided to the RF electrodes and may also preferably includes an indicator LED mounted to the handle, activated to indicate that delivery of RF energy is underway. The hemostat is usable with conventional RF generators. Alternatively, the hemostat may be used in conjunction with an RF generator system, which incorporates a transmural measurement and automatic shut off of ablation energy.

#### Brief Description of the Drawings

Figure 1 is a plan view of an assembled hemostat according to one embodiment of the present invention.

Figure 2 is an exploded view of the jaw assembly of the hemostat of Figure 1.

Figure 3A is a cross-section view through the jaw assembly of the hemostat of Figure 1.

Figure 3B is a cross-section view through lines 3B - 3B of Figure 3A.

5        Figure 4 is an end view in partial cross-section of the proximal end of the knuckle portion of the jaw assembly of the hemostat of Figure 1.

Figure 5A is a plan view of an elongated tubular electrode used in the hemostat of Figure 1.

10       Figure 5B is an enlarged cross-section view taken along lines 5B - 5B of the electrode illustrated in Figure 5A.

Figure 6A is an end view of an electrode support as used in the jaw assembly of the hemostat of Figure 1.

15       Figure 6B is a cross-section view taken along lines 6A - 6A of Figure 6A illustrating the electrode support.

20       Figure 7A is an end view of an electrode sheath as included in the jaw assembly of the hemostat of Figure 1.

Figure 7B is a cross-section view taken along lines 7B - 7B of Figure 7A illustrating the electrode sheath.

25       Figure 8A is a plan view of the right half of the handle employed in the hemostat of Figure 1.

Figure 8B is an enlarged plan view of the distal portion of the right handle half illustrated in Figure 8A.

30       Figure 8C is a cross-section view taken along lines 8C - 8C through the right handle half of the hemostat of Figure 1.

Figure 9A is a plan view of the left half of the handle employed in the hemostat of Figure 1.

5      Figure 9B is an enlarged plan view of the distal portion of the left handle half illustrated in Figure 9A.

Figure 9C is a cross-section view taken along lines 9C - 9C through the left handle half of the hemostat of Figure 1.

10     Figure 10 is an enlarged view of the trigger portion of a hemostat as in Figure 1 with the left handle half removed.

Figure 11A is a perspective view of a trigger lock as employed in the trigger assembly of the hemostat as in Figure 1.

15     Figure 11B is a plan view of the trigger lock of Figure 11A.

Figure 12A is a top plan view of a link arm as employed in the trigger assembly of an assembled hemostat as in Figure 1.

20     Figure 12B is a side plan view of the link arm of Figure 12A.

Figure 13A is a side plan view from the distal end of the trigger employed in the trigger assembly of the hemostat of Figure 1.

25     Figure 13B is a cross-section view taken along lines 13B - 13B through the trigger of Figure 13A.

30     Figure 14 is a cut-away view of the proximal portion of the hemostat of Figure 1 with the left handle half removed.

Figure 15A is a sectional view through an alternative embodiment of an upper and lower jaw for use with a hemostat otherwise as in Figure 1.

Figure 15B is a cross-sectional view taken along lines 15B - 15B of Figure 15A.

Figure 16A is a plan view of an electrode extension employed in the alternative embodiment of the upper and lower jaw depicted in Figures 15A and 15B.

Figure 16B is an expanded view of a barb of the electrode extension depicted in Figure 16A.

#### Detailed Description of the Preferred Embodiments

In reference to Figure 1, a preferred embodiment of the hemostat of the present invention generally comprises an elongated handle assembly or handle 10 having a jaw assembly 90 mounted at handle distal end 15, a trigger 20 intermediate the handle proximal and distal ends 95 and 15, and a strain relief 60 located at handle proximal end 95. An elongated cable is coupled to the strain relief 60 and comprises a fluid conduit 70 extending to a proximal fluid fitting 75 adapted to be coupled to a source of conductive fluid and a multi-conductor electrical cable 80 extending to a proximal electrical connector 85 adapted to be coupled to an electrosurgical unit. The trigger 20 is employed to move the jaws of the first or lower jaw assembly 40 with respect to the second or upper jaw assembly 30 of the jaw assembly 90 together to compress tissue therebetween to allow for creation of a linear RF ablation by electrically conductive fluid emitted from electrodes and contacting tissue or direct contact of the electrodes located along the upper and lower jaws 35 and 45.

The jaw assembly 90 includes the upper jaw assembly 30, the lower jaw assembly 40, and a swivel assembly 50, discussed in more detail below. The upper jaw and lower jaw assemblies 30 and 40 have opposed upper and lower jaws 35 and 45, respectively, each comprising a fluid assisted elongated electrode assembly. The upper and lower jaw assemblies 30 and 40 support elongated electrodes, discussed in more detail below, each coupled to one of the insulated conductors within conduit 70 extending



proximately through the strain relief 60 to electrical connector 85. Each of the jaws 35 and 40 of respective upper and lower jaw assemblies 30 and 40 are also coupled to fluid conduit 80 enabling delivery of saline or other conductive fluid from a source coupled to fitting 75 along the lengths of the opposed jaws 35 and 45.

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The swivel assembly 50, provides the physician with the opportunity to position the jaw assembly 90 in a variety of orientations relative to the handle 10, to facilitate placing the 35 and 45 jaws against tissue to form desired lines of lesions, e.g., the heart wall in performance of the above-described Maze procedure. The physician can manually grasp and rotate the swivel assembly 50 and the jaw assembly 90 to provide a roll adjustment R, preferably through an arc of at least 300 degrees, relative to the axis of the distal end 15 of the handle 10 through interaction of components of the handle and swivel assembly described further below. In addition, the physician can grasp the jaw assembly 90 and adjust it in pitch P relative to the swivel assembly 50 through the interaction of components of the jaw assembly 90 and the swivel assembly 50 described further below. Preferably, the available arc of pitch P adjustment extends over at least 90 degrees. Moreover, the upper and lower jaws 35 and 45 are malleable as described further below. The combination of these features and the S-shape handle 10 make the hemostat highly versatile in use.

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The trigger 20 is employed to open (separate apart) and close (draw together) the jaws 35 and 45 and to compress tissue between the jaws 35 and 45 prior to application of RF energy to create an elongated lesion. A thumb slide 25 is provided in conjunction with an internal trigger lock, allowing the position of the trigger 20 and the jaws 35, 45 to be locked. After the trigger 20 is drawn toward the handle 10 to close the jaws 35 and 45, the thumb slide 25 is moved distally relative to the handle 10 to cause an internal trigger lock to engage one of a series of ratcheting lock points that define a set of locking locations for the jaws 35, 45, as described further below. Movement of the thumb slide 25 proximally relative to the handle 10 releases the trigger 20 and the jaw assembly 90, allowing the jaws 35, 45 to return to a fully open position. The interaction of the trigger 20, thumb slide 25 and the associated trigger lock mechanism frees the physician from the need to maintain pressure on the trigger 20 to compress

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tissue between the jaws 35, 45 during the ablation, simplifying operation of the hemostat.

Referring to Figure 2, the upper jaw assembly 30 includes a pivotable, relatively rigid, upper jaw mount 300, an elongated backbone 310, an elongated insulated electrode sheath 320, an elongated conductive electrode 330, and an elongated electrode support 340. Upper jaw mount 300 may be fabricated of plastic or other insulated material, and in preferred embodiments may be fabricated of Teflon filled polycarbonate plastic. Backbone 310 is preferably fabricated of malleable stainless steel or other malleable metal and is attached at a proximal end to upper jaw mount 300. An insulated electrode sheath 320 is fitted over spine 310 with its proximal end located adjacent upper jaw mount 300. The elongated conductive electrode 330 comprises a length of malleable conductive metal tubing as shown in Figures 5A and 5B is fitted into a lumen of the elongated electrode support 340. The insulated electrode sheath 320 is formed with a channel that receives the sub-assembly of the elongated conductive electrode 330 and electrode support 340 disposed along the jaw 35. Electrode sheath 320 may be fabricated of a flexible, electrically insulating, material, for example, silicone rubber. Elongated electrode support 340 is preferably fabricated of a porous material, such as Porex<sup>TM</sup> plastic, allowing for conductive fluid infiltration through its sidewall along its length and correspondingly delivery of conductive fluid along the length of jaw 35. The jaw 35 can therefore be bent laterally with respect to the upper jaw mount 300 to form a curve along the length thereof.

The lower jaw assembly 40 also includes a relatively rigid, lower jaw mount 400, an elongated backbone 410, an elongated insulated electrode sheath 420, an elongated conductive electrode 430, and an elongated electrode support 440 that are all formed of the same materials as the corresponding elements of the upper jaw assembly 30. The assembly of the elongated backbone 410, elongated insulated electrode sheath 420, elongated conductive electrode 430, and elongated electrode support 440 is also shown in FIG. 3B.

The jaw 45 can therefore also be bent laterally with respect to the lower jaw mount 400 to form a curve along the length thereof. In use, the physician manually forms a lateral curve in both the upper and lower jaws 35 and 45 to fit the contour of the tissue, e.g., the heart wall.

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The lower jaw mount 400 is formed with a pair of spaced apart, parallel, plates or flanges 401 and 403 each bearing a series of notches 402 and 404, respectively, along the edges thereof. When assembled, a proximal portion of the upper jaw mount 300 is fitted between the flanges 401 and 403. A pin 480 extends through aligned holes through the proximal portion of upper jaw mount 300 and the flanges 401 and 403. The ends of pin 480 are fixed to the flanges 401 and 403 allowing the proximal portion of the upper jaw mount 300 to be rotated about the pin 480, thereby allowing jaws 35 and 45 to open and close. The upper and lower jaws 35 and 45 are separated apart a predetermined distance in the fully closed positions although the electrically insulated distal ends of the insulated electrode sheaths 320 and 420 may contact one another. A spring 450 urges the upper and lower jaws 35 and 45 apart from one another, facilitating opening of the jaws 35 and 45 upon release of the trigger 20 after application of RF energy.

As shown in Figures 2 and 3A, the swivel assembly 50 includes a swivel 500 that may also be fabricated of Teflon filled polycarbonate plastic to have a tubular proximal swivel portion 506, a pair of parallel plates or flanges 502 and 504 extending distally from swivel proximal portion 506 and a extending detent 501 extending laterally between flanges 502 and 504. The jaw assembly 90 is mounted to the swivel assembly 50 by outwardly and laterally extending bosses 405 on the outer surfaces of flanges 401 and 403 that are fitted into bores 503 through swivel flanges 502 and 504. The upper jaw mount 300 is mounted to the lower jaw mount 400 by pin 480 as described above, and the lower jaw mount is 400 pivotably mounted relative to the swivel 500. Therefore, the upper and lower jaw assemblies 30 and 40 may be pivoted together relative to the swivel 500, allowing for movement of the jaws 35 and 45 together through the range of pitch P adjustment. The selected pitch P adjustment is maintained by the engagement of the detent 501 into an opposed pair of notches 402

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and 404, stabilizing the upper and lower jaws 35 and 45 in a desired orientation relative to the swivel assembly 50. In use, the physician adjusts the relative positions of the jaws 35 and 45 relative to the swivel assembly 50 by simply manually moving the jaw assemblies 30 and 40 in the pitch P direction around the pivot axis defined by  
5       bosses 405 within the corresponding bores 505 in swivel flanges 502 and 504. The detent 501 simply rides over the ridges separating adjacent notches 402 and 404.

As noted above, the swivel assembly 50 and the upper and lower jaw assemblies 30 and 40 can be rotated around the axis of the distal end 15 of the handle 10 to a desired  
10       roll adjustment R to facilitate positioning the jaws 35 and 45 for creation of elongated lesions. The proximal portion 506 of swivel 500 is rotatably mounted within a collar 550 that is mounted fixedly to the distal end 15 of the handle 10 as shown in Figure 3A. The collar 550 has a wavy or sinusoidal distally facing surface 551 of collar 550. A washer-shaped insert 510 having a wavy or sinusoidal proximally facing surface  
15       511 is fitted over the elongated proximal portion 506 of swivel 500 and attached to the swivel 500 through notches 514, engaging corresponding bosses 557 and 567 (shown in FIG. 4) formed on swivel 500. A C-clip 524 mounted in a circumferential groove formed in the proximal portion 506 of swivel 500 maintains the proximal portion 506 within the lumen of collar 550. A spring washer 522 and a flat washer 520 are  
20       interposed between the C-clip 524 and the proximal end of collar 550. Spring washer 522 urges the wavy or sinusoidal surfaces of collar 550 and insert 510 against one another, whereby a plurality of detent locations are defined that maintain a selected roll R adjustment relative to the distal end 15 of the handle 10. In use, the physician adjusts the roll R of the jaw assembly 90 by simply turning the swivel assembly 50  
25       relative to the handle 10. The detent mechanism maintains the swivel assembly 50 in the selected desired roll R adjustment prior to and during closure of the jaws 35, 45 to compress tissue during application of RF energy.

A cable 390 is also shown in Figures 3A and 4 that extends from the trigger 20 and  
30       that is employed to open and close the jaws 35 and 45. Cable 390 passes through the internal lumen of proximal swivel portion 502, through cable bore 565, around shoulder 404 of lower jaw mount 400, around boss 303 in upper jaw mount 300 and

then upward into bore 408 in lower jaw mount 400. The distal end of the cable 390 is maintained within bore 408 by ball 350. When the cable 390 is pulled proximally by squeezing trigger 25, boss 303 of upper jaw 300 is pulled toward bore 408 in lower jaw 400, thereby pulling upper jaw 35 toward lower jaw 45, allowing for compression of tissue there between. It should be noted that during this operation, the lower jaw mount 400 remains fixed relative to the swivel assembly 50 and only upper jaw mount 300 moves relative to the swivel assembly 50 or the handle 10. Proximal movement of cable 380 does not affect the position of the lower jaw 45 relative to the handle 10, nor does it affect the selected roll R adjustment of swivel 500. Rotation of the jaw assembly 90 and swivel 500 about the roll axis does not affect the operation of the cable 390 because the cable 390 passes through the swivel 500 and enters the jaw assembly 90 along the roll axis. Pitch P adjustment of the jaw assembly 90 does not significantly effect operation of the cable 390 in opening or closing the jaws 35, 45 because shoulder 404 is at the center of rotation of lower jaw mount 400 relative to swivel 500 and remains essentially in the same location regardless of the pitch P adjustment.

Figures 3A and 4 also internal electrical wiring and fluid delivery conduits of this embodiment of the invention including, insulated conductors 360 and 460 and fluid conduits 370 and 470 that both terminate at connections with the proximal ends of the upper and lower electrodes 330 and 430, respectively. The fluid conduits 370 and 470 deliver conductive fluid into the lumens of the tubular upper and lower electrodes 330 and 430, respectively. As shown in Figure 4, the upper insulated conductor 360 and the upper fluid conduit 370 are routed to one side of the cable 390, and the lower insulated conductor 460 and the lower fluid conduit 470 are routed to the other side of the cable 390 while passing through the lumen 534.

The elongated tubular electrodes 330 and 430 are illustrated in Figures 5A and 5B. The tubular electrodes 330 and 430 are preferably formed of thin-walled, malleable stainless steel tubing extending between a proximal open end 331, 431 and a distal closed end 333, 433. A series of fluid ports 335, 435 are formed, e.g., by laser drilling, through the sidewall of the tubing from the lumen 339, 439 and extending in

a single line, although the fluid ports could be formed in any selected array extending around the circumference of the sidewall of the tubing. The proximal ends 331, 431 are notched in alignment with the series of fluid ports 335, 435 to assist in assembly so that the fluid ports 335, 435 are directed in a particular alignment with the porous electrode support 340, 440.

The porous electrode support 340, 440, depicted in Figures 6A and 6B, comprises a length of non-conductive, porous, malleable tubing having a channeled side 343, 443 adapted to fit within an elongated channel 323, 423 of the insulated electrode sheath 320, 420, depicted in Figures 7A and 7B. The porous electrode support 340, 440 is conically shaped at the support distal end 347, 447 to fit within a conically shaped terminus 327, 427 of the elongated channel 323, 423 of the insulated electrode sheath 320, 420. During assembly, the elongated tubular electrode 330, 430 is inserted into the elongated lumen 341, 441 of the porous electrode support 340, 440. Preferably, the series of fluid ports 335, 435 are oriented toward the channeled side 343, 443 so that the conductive fluid emitted from the lumen through the series of fluid ports 335, 435 then migrates laterally through the pores of the porous electrode support 340, 440 and around its circumference to thoroughly and uniformly wet the porous electrode support 340, 440 along the upper and lower jaws 35 and 45.

The sub-assembly so formed is fitted into the shaped terminus 327, 427 and the elongated channel 323, 423 of the insulated electrode sheath 320, 420 as also shown in Figures 3A and 3B. Adhesive is applied to the contacting surfaces 323, 343 and 423, 443 to maintain the sub-assembly of the elongated tubular electrode 330, 430 inserted into the elongated lumen 341, 441 of the porous electrode support 340, 440 affixed to the insulated electrode sheath 320, 420. The adhesive does not block migration of conductive fluid around the porous electrode support 340, 440. Electrode sheath 320, 420 is also formed having an elongated tapered internal recess 421 441 that receives the malleable backbone 310, 410 as shown in Figures 2 and 3. Again, adhesive may be applied to the contacting surfaces of the backbone 310, 410 and the elongated tapered internal recess 421 441.

The handle 10 is formed of a right handle half 600 depicted in Figures 8A - 8C and a left handle half 700 depicted in Figures 9A - 9C. Trigger sections 620 and 720 of the respective right and left handle halves 600 and 700 include downwardly opening recesses 621 and 721 in which trigger 20 is mounted (as shown in Figures 1 and 10) to pivot inward to apply tension on cable 390 or outward to release tension on cable 390. Upward openings 627 and 727 in respective right and left handle halves 600 and 700 receive the thumb slide 25. Inwardly extending projections 630 and 730 are also formed in respective right and left handle halves 600 and 700 that function to constrict the fluid conduits 370 and 470 to prevent conductive fluid flow therethrough when the trigger 20 is released as described further below.

A set of circular matching, laterally opposed, sockets 623 and 723 are formed in the interior surfaces of the respective right and left handle halves 600 and 700. The set of sockets 623, 723, receive a pair of pivot bosses 206, 206' of trigger 20 (shown in Figure 13A) about which the trigger 20 pivots as described further below.

A set of matching, laterally opposed, and slightly elongated or oblong, sockets 624 and 724 are formed in the interior surfaces of the respective right and left handle halves 600 and 700. The set of sockets 624, 724 receive and guide a trigger lock 27 (shown in Figures 11A and 11B) that interacts with trigger 20 as described further below. The oblong shape of the set of sockets 624, 724 assists in allowing the trigger 20 to ratchet along the trigger lock 27 when trigger is drawn inward to tension the cable 390 during closing of the jaws 35, 45 as described further below.

A further set of matching, laterally opposed, elongated sockets 625 and 725 are also formed in the interior surfaces of the respective right and left handle halves 600 and 700. The set of sockets 625, 725 receive and guide a link arm 26 (shown in Figures 12A and 12B) that interacts with trigger 20 as described further below.

As shown in Figures 8B and 9B, the distal portions of right and left handle halves 600 and 700 are formed with internal cylindrical recesses or sockets 612 and 712 that receive the laterally extending bosses 552 of collar 550 (Figure 2). Internal grooves 611 and 711 are also formed within the distal portions of right and left handle halves

600 and 700 in which the c-clip 524, flat washer 520 and spring washer 522 (Figures 2 and 3A) are fitted.

As shown in Figures 8C and 9C, the right and left handle halves 600 and 700 are also provided with a series of laterally extending, perpendicular internal walls 628 and 728 that include slots and recesses for routing the fluid conduits or tubes 370 and 470, the cable 390 and the insulated wire conductors 360 and 460 that extend through the length of handle 10.

The trigger 20, thumb slide 25, and the associated link arm 26 and trigger lock 27 are shown assembled to the right handle half 600 in Figure 10 with the trigger 20 in the released position and the thumb slide 25 in the unlocked distal or retracted position. The trigger lock 27 is shown in greater detail in Figures 11A - 11B, the link arm 26 is shown in greater detail in Figures 12A - 12B, and the trigger 20 is shown in isolation in Figures 13A - 13B.

Trigger 20 is provided with laterally extending cylindrical pivot bosses 206, 206' that are mounted into sockets 723 and 623, respectively. When released, trigger 20 extends outward through downwardly opening recesses 621 and 721. When pulled, trigger 20 is pivoted inwardly into the handle recesses 621 and 721 about pivot bosses 206, 206' to apply tension to the cable 390 that draws the upper and lower jaws 35 and 45 together. Cable 390 is mounted within a lubricious tube 391, extending from the proximal wall 628 to the distal end 15 of the handle 10, to allow the cable 390 to move freely within the handle 10 when trigger 20 is pulled or released.

Trigger 20 is coupled to the proximal end of cable 390 through link arm 26, illustrated in isolation in Figures 12A and 12B. Link arm 26 is provided at a distal end with two laterally extending bosses 262 and 262' that are received in circular sockets 204 (one of which is shown in Figure 13B) formed on the interior walls of the internal chamber 202 of trigger 20 to thereby pivotally mount the distal end of the link arm 26 to the trigger 20. Link arm 26 is formed with a longitudinally extending slot 266, allowing compression of the distal end of the link arm 26 to facilitate positioning of cylindrical



bosses 262 and 262' within the corresponding sockets 204 within the trigger 20. As also shown in Figure 13B, longitudinal slots 215 are provided in the interior 202 to assist insertion of the bosses 262, 262' on link arm 26 into sockets 204 in trigger 20 during assembly. Link arm 26 is provided at its proximal end with two laterally  
5 extending, circular bosses 264 and 264' that are received within the elongated slots 625 and 725, respectively, in the respective right and left handle halves 600 and 700. When trigger 20 is released, the circular bosses 264 and 264' are disposed at the distal ends of the opposed elongated slots 625 and 725, respectively. When trigger 20 is pulled inward, the proximal end of the link arm 26 is moved proximally within the  
10 opposed slots 625 and 725, applying tension to cable 390.

Cable 390 is coupled to the link arm 26 by means of a swaged retainer 24, mounted within a coil spring 28. Coil spring 28 is fitted within a generally cylindrical chamber 266 formed extending at 90 degrees to the proximal end of link arm 26. Cable 390  
15 passes through an upwardly facing slot 270 in link arm 26 and through the interior of spring 28 to retainer 24. Spring 28 is normally extended within chamber 266 but is compressed to provide protection against over tensioning of the cable 390, if the upper and lower jaws 35 and 45 encounter significant resistance to further movement toward one another. The configuration of the trigger 20, link arm 26 and slots 625 and 725  
20 provide a mechanism whereby, the cable 390 is pulled proximally relatively quickly during initial upward movement of the trigger 20 to facilitate initial rapid closing of the jaws 35 and 45. The cable 390 is pulled relatively more slowly during further upward movement of the trigger 20 to provide increased control to the physician during final compression of the jaws 35 and 45 against the tissue to be ablated.

25 Trigger 20 is also provided with a distally extending projection 208 terminating with a laterally extending, generally cylindrical, boss 210 shown best in Figure 13B. As illustrated in Figure 10, when the trigger 20 is released and in its most downward position (corresponding to the point of maximum jaw opening), the fluid conduits or  
30 tubes 370 and 470 are disposed side by side and compressed between cylindrical boss 210 and the inwardly extending projections 630 and 730. This compression of the fluid conduits or tubes 370 and 470 prevents flow of conductive fluid from the fluid

source and out of the electrodes 330 and 430 and the electrode mounts 340 and 440 when the hemostat is not in use.

5 The trigger 20 is also formed with a laterally extending slot 212 having an array of teeth 214 formed along one side of the slot 212. A trigger lock mechanism is provided involving the interaction of the thumb slide 25 with the trigger 20 through a trigger lock 27 that is coupled at one end with the thumb slide 25 and selectively engages the teeth 214 to retain the upper and lower jaws 35 and 45 at a fixed position adjacent tissue to be ablated without requiring the physician to continually apply  
10 pressure to trigger 20. Distal or forward movement of the thumb slide 25 causes the trigger lock 27 to engage the teeth 214, and proximal or rearward movement of the thumb slide 25 releases the engagement. The trigger 20 can be operated freely by the physician to open or close the upper and lower jaws 35 and 45 when the thumb slide 25 is in the rearward position. With the thumb slide 25 in the forward position, the  
15 trigger 20 can be moved inward ratcheting over the teeth 214 to close the upper and lower jaws 35 and 45, but the trigger 20 will not move outward upon release by the physician.

20 The trigger lock 27 depicted in isolation in Figures 11A and 11B comprises an elongated link arm 275 having rods 272 and 278 laterally extending parallel to one another from opposed ends of the link arm 275. As shown in Figure 10, the rod 272 is inserted through the slot 202 so that the link arm 275 extends alongside the trigger 20 within the recess 721. The rod 278 extends into a generally centrally located notch 252 of a resilient beam section 250 of the thumb slide 25. Cylindrical pivot bosses  
25 276 and 276' extend laterally on either side of the link arm 275 in alignment with rod 272 and are inserted into sockets 724 and 624, respectively.

30 The rod 272 inserted through the slot 212 extending through the trigger 20 is formed with a laterally extending ramped tooth 274 that is selectively engagable with one of the ramped teeth 214 formed along the proximal edge of slot 212, when the trigger lock 27 is pivoted forward from the position illustrated in Figure 10 by distal or forward movement of the thumb slide 25 by the physician. Movement of the trigger

20 inwardly into the handle recess with the trigger lock 27 advanced forward from the position illustrated in Figure 10 causes the interaction of the tooth 274 on the trigger lock 27 with the teeth 214 to retain the trigger 20 in position when pressure is released. The oblong configuration of sockets 624 and 724 that receive bosses 276' and 276 of the trigger lock 27 allow the trigger lock 27 to move slightly forward during inward movement of the trigger 20 so that the tooth 276 on trigger lock 27 may ratchet along the ramped teeth 214 of trigger 20. Interaction of the teeth 214 with the ramped tooth 274 on the trigger lock 27 prevents outward movement of the trigger 20 as long as the thumb slide 25 remains in the forward position in the slot formed by openings 627 and 727.

Release of the trigger 20 is accomplished by proximal or rearward movement of thumb slide 25, pivoting the ramped tooth 274 out of engagement with a tooth of the teeth 214 along slot 212 which allows the upper and lower jaws 35 and 45 to open unless the physician holds the trigger 20 in position. The trigger 20 is urged outwardly out of the recess in handle 10 by spring 23 upon release of the trigger 20 and rearward movement of the thumb slide 25. When the trigger 20 reaches its full outward position, flow of conductive fluid through fluid conduits 370 and 470 is terminated as the tubing is compressed between the laterally extending boss 210 and the inwardly extending projections 630 and 730, as discussed above.

The thumb slide 25 is provided with a resilient beam section 250, having a generally centrally located notch 252 which engages the laterally extending rod 278 on trigger lock 27, coupling the thumb slide 25 to the trigger lock 27. The thumb slide 25 is preferentially retained at either the proximal, rearward or distal, forward point of its travel, without the necessity of the physician manually maintaining pressure on the thumb slide 25 due to the resilience of the beam 250 and the arcuate path of travel of the rod 278.

Figure 14 illustrates a proximal portion of the assembled hemostat of Figure 1 with the left handle half 700 removed to show the multi-conductor cable 80 and fluid

conduit 70 extending through the strain relief 60 and their joinder to the wire conductors 360, 460 and the fluid conduits 370, 470.

5 The distal end of the fluid conduit 80 is coupled through a fitting 802 to proximal end of flexible tubing 804. The distal end of flexible tubing 804 is coupled to the trunk of a Y-connector 806, and the distal legs of the Y connector 806 are coupled to arms of a D-connector 810. The D connector 810 is formed of a flexible plastic, e.g., silicone rubber, providing spaced apart fluid channels that are coupled to the proximal ends of the fluid conduits 370 and 470.

10 The fitting 804 supports a proximal flow controller or regulator 820 that has a precisely sized orifice that limits conductive fluid flow into the Y-connector 806. The flow regulator 820 establishes a fixed flow rate and pressure within the Y-connector 806 regardless of the pressure of the fluid source that is available in the surgical theatre. The flow rate is established depending upon the upper and lower electrode area and design.

15 The D connector 810 supports a pair of downstream flow regulators 822 and 824 that have equal, precisely sized orifices that further reduce the fluid flow rate and pressure of the conductive fluid entering the fluid conduits 370 and 470. The downstream flow regulators 822 and 824 ensure that an even flow of conductive fluid is provided from within the Y connector 806 into the fluid conduits 370 and 470. By this mechanism, the hemostat may be operated without the necessity of an associated pressurized fluid source and still provide controlled and even fluid flow to the upper and lower jaws 35 and 45 that contact the tissue to be ablated.

20 The D connector 810 supports a pair of downstream flow regulators 822 and 824 that have equal, precisely sized orifices that further reduce the fluid flow rate and pressure of the conductive fluid entering the fluid conduits 370 and 470. The downstream flow regulators 822 and 824 ensure that an even flow of conductive fluid is provided from within the Y connector 806 into the fluid conduits 370 and 470. By this mechanism, the hemostat may be operated without the necessity of an associated pressurized fluid source and still provide controlled and even fluid flow to the upper and lower jaws 35 and 45 that contact the tissue to be ablated.

25 An optional light emitter, e.g., an LED 830, is depicted in Figure 14 located within the strain relief 60 and coupled through an electrical junction 832 with the insulated wire conductors 360 and 460. The wire conductors 360 and 460 can take the form of a twisted wire cable that extends distally from the electrical junction 832 through the length of the handle to the swivel assembly 50 where they are separated as shown in Figures 3A and 4. Separate wire conductors within a cable 834 extend from the

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electrical junction 832 to the LED 830. In use, the LED 830 is illuminated in response to activation of an associated RF electrosurgical generator, and the LED illumination illuminates the strain relief 60, which is preferably fabricated of a translucent flexible material, such as silicone rubber or the like. The physician will typically hold the handle 10 in orientations that make the strain relief 60 visible, and illumination of the LED 830 indicates to the physician that RF energy is being applied to the electrodes

The proximal portion of the handle 10 may also optionally carry other electronic components including circuitry containing calibration information, for example calibrating a thermocouple if provided to sense electrode or tissue temperature. Circuitry containing identification information or providing re-use prevention may also be included, however such features are not believed to be essential to or a part of the present invention.

Figures 15A and 15B illustrate an alternative embodiment of the electrode described above that can be employed in modified upper and lower jaw assemblies 30A and 40A corresponding generally to upper and lower jaw assemblies 30 and 40. The upper and lower jaw assemblies 30A, 40A have a malleable backbone 310, 410 and a sheath 320, 420 as described above that are attached to the respective upper and lower jaw mounts 300 and 400 as shown in Figures 2 and 3. However, electrode 330A, 430A incorporates an exposed elongated electrode extension 350A, 450A extending to the outer surface of porous electrode support 340A, 440A and along the jaw 35, 45 that is intended to directly contact the tissue to be ablated. In this embodiment, conductive fluid is delivered as described above into the lumen of the internal tubular electrode 330A, 430A, which may be substantially the same as the tubular electrodes 330, 430. An elongated electrode surface 352A, 452A of the electrode extension 350A, 450A and the contacted tissue are irrigated by conductive fluid emitted through the fluid ports of the internal tubular electrode 330A, 430A and conducted through the pores of the electrode support 340A, 440A.

The electrode extension 350A, 450A is depicted prior to assembly with the electrode support 340A, 440A and the elongated tubular electrode 330A, 430A in Figures 16A and 16B. As formed, the electrode extension 350A, 450A includes an elongated straight portion 352A, 452A that is mounted against the exposed to the exterior of the electrode support 340A, 440A. A distally extending portion 360A, 460A is adapted to be inserted into the lumen of the electrode support 340A, 440A to extend alongside the elongated tubular electrode 330A 430A as shown in Figure 15B.

A series of barbed projections 354A, 454A extend laterally away from the elongated straight portion 352A, 452A. The electrode extension 350A, 450A is adapted to be bent back at junction 356A, 456A to enable insertion of the series of barbed projections 358A, 458A into the electrode support 340A, 440A. The proximal end 362A, 462A is electrically connected to the proximal ends of the tubular electrodes 330A, 430A and the distal ends of the wire conductors 360, 460.

This alternative exposed electrode embodiment can be formed by modifying the tubular electrode 330, 430 to have a conductive electrode band extending from the tubular electrode along the surface of the electrode support 340, 440. Alternatively, this alternative electrode design can be accomplished without use of the tubular electrode 330, 430, whereby conductive fluid is delivered to a lumen of the electrode support 340, 440 or to a fluid channel between the electrode support 340, 440 and the sheath 320, 420, and the exposed electrode band is supported by the electrode support 340, 440.

The embodiments of the electrosurgical hemostat described above contain a number of valuable features and components, all of which contribute to provide a hemostat, which is convenient to use while providing substantial flexibility in use. However, many of the features of the hemostat could be employed in hemostats of other designs. For example, the trigger mechanism and/or the trigger lock mechanism of the above-described hemostat would certainly be of use in conjunction with cable activated hemostats having jaws of alternative designs to that described above. Similarly, the jaw assembly of the present hemostat might well be employed in conjunction with

alternative trigger mechanisms. And/or in conjunction with alternative electrode designs, including electrodes which might not include provision for fluid irrigation and/or in the context of the hemostat having jaws that are rigid and not malleable by the physician to assume desired configurations. Further the specific electrode design  
5 employed in the hemostat design described above would be of significant use in conjunction with other hemostat types, including hemostats having jaws which are moved toward one another by alternative mechanisms. Similarly, a strain relief of the type described above including an LED indicator is believed to be of value in conjunction with any number of electrosurgical tools, particularly those in which the  
10 strain relief is within the physician's field of view, during normal operation of the hemostat. As such, the above description should be taken as exemplary, rather than limiting, with regard to the claims which follow.

In conjunction with the above specification, we claim: